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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/818,466 | 03/27/2001 | Sean Lee | 099866/9 | 1836 |

31013 7590 09/10/2004

KRAMER LEVIN NAFTALIS & FRANKEL LLP
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| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/818,466 | LEE ET AL. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *135-170* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *135-170* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114 and the request for extension of time (3 months-granted), both filed 04/14/04 is acknowledged.

Claims 135-170 are pending. Claims 135-170 are rejected.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 135-138 and 153-156 are rejected under 35 U.S.C. 102(e) as being anticipated by LaTorre *et al.* (US Pat. No. 6,517,863 B1).**

LaTorre *et al.* disclose compositions and methods for treating nails and adjacent tissues comprising particles of bioactive glass that have anti-microbial properties, alone or in combination with therapeutic agents, hydrophilic polymers and other additional agents (see Abstract). The bioactive glass composition can be prepared in several ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles (col. 4, lines 33-45).

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 135-138 and 153-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaTorre *et al.* (US Pat. No. 6,517,863 B1).**

LaTorre *et al.*, as delineated above, teach compositions and methods for treating nails and adjacent tissues comprising particles of bioactive glass that have anti-microbial properties, alone or in combination with therapeutic agents, hydrophilic polymers and other additional agents (see Abstract).

According to LaTorre *et al.*, the bioactive glass composition can be prepared in several ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles (col. 4, lines 33-45). The bioactive glass has a particle size of less than about about 5 microns and can

be in the form of a suspension, lotion, cream (water-in-oil emulsion), gel or extract (col. 4, lines 27-32; 51-67).

LaTorre *et al.* disclose that the bioactive glass compositions can include additional components, such as antibiotics, antivirals, antifungals, biotin, collagen, amino acids, proteins, vitamins, penetration enhancers, permeation/binding agents, dyes, fragrances and other cosmetically useful additives (col. 2, lines 62-66). Bioactive glass also has anti-microbial properties (col. 2, line 67).

The Examples at columns 6-7 demonstrate various bioactive glass formulations for application to a nail surface. For instance, Example 1 at column 6, line 45 demonstrates a bioactive glass preparation whereby 0.2 grams of Bioglass® with a particle size of less than 20 microns was mixed with an equal volume of water to form a paste. The paste was applied to the nails of one hand and allowed to dry. This procedure was repeated and after two applications of the Bioglass® powder, there was a discernable difference in the strength and hardness of the nails treated with the Bioglass® powder, compared to the untreated control.

**Claims 139-152 and 157-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaTorre *et al.* (US Pat. No. 6,517,863 B1) as applied to claims 135-138 and 153-156 above and further in view of Vatter *et al.* (US Pat. No. 6,224,888 B1).**

The teachings of LaTorre *et al.* have been discussed above. LaTorre *et al.* do not teach cosmetic additives, such as jojoba oil, glycerin, parabens and pigments. It is obvious to one of ordinary skill in the cosmetic art to include additives, such as oils, waxes, pigments and the like. Such skill is also evident from the reference of Vatter *et al.*

**Vatter *et al.*** teach cosmetic compositions comprising various additives, such as oils, waxes, pigments, preservatives, colorants, fragrances and the like. Suitable oils include *jojoba oil, mineral oil, castor oil, etc.* (see reference column 6, lines 19-35). Waxes include *carnauba, candelilla, ozokerite, microcrystalline waxes and mixtures thereof* (col. 8, lines 31-44). *Pigments, dyes and talc* are disclosed at column 10, line 64-col. 11, line 49. Vitamins taught include *Vitamin A and E* (col. 12, lines 20-29). *Glycerine* is disclosed at column 5, lines 8-13. Parabens, such as *methyl paraben and propyl paraben* are disclosed in various examples, particularly Example 14. Vatter *et al.* teach that the cosmetic compositions can be, for instance, in the form of foundations, eye shadows, blushers, lipstick, lipcare products, mascara, solutions, powders and the like (col. 2, lines 16-21); (col. 12, lines 2-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined reference teachings of Vatter *et al.* within LaTorre *et al.* to obtain improved personal care compositions containing an array of beneficial additives because Vatter *et al.* expressly teach cosmetic compositions comprising routinely utilized additives, such as oils, waxes, pigments, vitamins, preservatives and the like for skin, hair and nails and similarly, LaTorre *et al.* teach a cosmetic composition for treating nails and adjacent tissues. The expected result would be an enhanced, beneficial cosmetic composition.

In summary, there is no significant distinction observed between the instant invention and the prior art, since the prior art explicitly teaches cosmetic formulations comprising bioactive glass and further teaches that it is well-known to use cosmetically-formulated additives and ingredients in a variety of make-up products. Thus, the instant invention as a whole would have

been obvious to one of ordinary skill in the art at the time of the invention. Hence, the instant invention is rendered *prima facie* obvious over the cited art of record.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Pat. No. 4,814,165 Berg *et al.* 03/1989

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*H. N. Sheikh* H.N.S.

Patent Examiner

Art Unit 1615

August 31, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600